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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,591	08/19/2003	Takaaki Isshiki	0020-5166P	2938
2292 7590 07/25/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER THALER, MICHAEL H	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 07/25/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

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<b>Office Action Summary</b>	<b>Application No.</b> 10/642,591	<b>Applicant(s)</b> ISSHIKI ET AL.	
	<b>Examiner</b> Michael Thaler	<b>Art Unit</b> 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2007 has been entered.

Claims 1, 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116). Khosravi discloses sheath (the portion of sheath 52 which has the enlarged distal region of lumen 64 as described in col. 5, lines 19-22) being closed at the proximal end (by the narrow proximal region described in col. 5, lines 19-25), a flexible shaft (the combination of shaft 12 and member 54 which is attached thereto as indicated in col. 5, lines 32-35, and noting that shaft 12 is flexible in the embodiment described in col. 4, lines 13-16 due to the articulations therein), the flexible shaft being a wire member (Shaft 12 and attached member 54 together are a "wire" member since this member is very thin, as indicated in col. 5, lines 39-42, and elongated. The fact that the member has a passageway through it does not preclude it from being a wire. For example,

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some guide wires have an elongated passageway through them for fluid delivery. Yet, they are wires.), thrombus capture member 14, 16 comprising a plurality of wires 24 forming a frame and having a configuration swollen in the middle portion and mounted slidably on shaft 12 at the distal end but fixed on the shaft at the proximal end thereof (col. 4, lines 24-27). Khosravi fails to disclose the filter frame wires 24 as being spiral and crossed with one another. However, Brooks et al. teach that filter frame wires 56 for supporting an endovascular filter membrane should be spiral and crossed with one another (col. 4, lines 37-43) apparently in order to obtain the advantage of better supporting the filter membrane around its circumference. It would have been obvious to make the Khosravi filter frame wires 24 spiral and crossed with one another so that it too would have this advantage. As to claim 4, Khosravi fails to disclose a hemostatic valve and a tubular member to hold it. However, it is old and well known to use hemostatic valves and tubular members to hold them in surgical devices in order to obtain the advantage of preventing blood loss. It would have been obvious to include a hemostatic valve and tubular member to hold it in the Khosravi device so that it too would have this advantage. The proximal portion of shaft 12 of Khosravi protrudes from the sheath 52 when the shaft 12 is inserted

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therein as described in col. 5, lines 51-56. As to claim 7, Khosravi fails to disclose the slide ring assembly as comprising an inner ring and an outer ring with the wires sandwiched therebetween. However, it is old and well known in this art to secure wires between inner and outer rings in order to obtain the advantage of providing a strong attachment between the wires and ring assembly. It would have been obvious to so construct the sliding ring in the Khosravi device so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above, and further in view of Rosenbluth (WO 99/56801). As to claim 5, Khosravi fails to disclose a side hole and second lumen in the sheath. However, Rosenbluth teaches that a sheath 11''' for an intravascular filter should include a side hole 310 and second lumen 309 in order to obtain the advantage of permitting rapid exchange of the sheath (page 18, lines 13-22). It would have been obvious to include a side hole and second lumen in the Khosravi sheath so that it too would have this advantage. As to claim 6, Khosravi fails to disclose a side infusion tube.

However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side infusion port 15 attached thereto in order to obtain the advantage of permitting injection of contrast medium into the vessel (page 15, lines 15-24). It would have been obvious to include a side infusion port in the Khosravi device so that it too would have this advantage.

Applicant's arguments filed June 14, 2007 have been fully considered but they are not persuasive. The allegation near the top of page 7 of the response that the dense braid/less dense braid frame configuration of Brooks et al. is only used to obviate the need for a filter material is incorrect. The dense braid/less dense braid frame configuration is disclosed as being used with the separate filter material wherein the filter material is located on the distal portion 60 having the dense braid noting col. 4, lines 39-43. Note the term "Alternatively" in col. 4, line 44 which begins the sentence referring to the embodiment having no separate filter material. Applicant alleges in the paragraph bridging pages 8 and 9 of the response that sheath 52 of Khosravi is never closed at the proximal end since bumper 54 with lumen 70 (receiving a guidewire therein) passes through the narrow proximal region. However, applicant considers the proximal end of sheath 1 of applicant's invention to be "closed" by a "closing member" 12 even though the closing

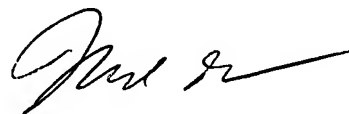
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member 12 has a hole 121 therein which receives shaft 2. Similarly, the proximal end of the Khosravi sheath is "closed" by a "closing member" (the narrow proximal region of sheath 52) even though the closing member has a hole therein which receives shaft 54 and a guidewire 69. As to the argument on page 9 of the response, shaft 12 of Khosravi is flexible at articulations described in col. 4, lines 13-16 which make the shaft flexible as stated in col. 4, lines 15-16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571) 272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

mht



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731